

REMARKS

Claims 1-6, 10-11, 24-30, 33-40, 44-49, 57, 61, and 75-76 are pending. Claims 1-6, 10-11 and 57-61 and 75-76 are under examination. Applicants appreciate the Examiner's indication that claims 5, 6, 10, 75, and 76 are allowed. Reconsideration of the remaining claims is respectfully requested.

Claim 1 has been amended to delete the recitation "or a homologue thereof." Claim 11 has been amended to insert the term "isolated." Claim 57 has been amended to correct a typographical error. Support for the amended claims can be found in the originally filed claims and throughout the specification. No new matter has been added.

Claim 57 was objected to because of the recitation of "alanine" instead of "adenine." The claim has been amended accordingly. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 11 was rejected under 35 U.S.C. §101 as being directed to nonstatutory subject matter. It is the Examiner's position that a "host cell comprising" includes a naturally occurring product. Claim 11 has been amended to recite "an isolated host cell," as helpfully suggested by the Examiner. Withdrawal of the rejection is respectfully requested.

Claims 1-4, and 57 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while considered by the Examiner to be enabling for an isolated human alpha-synuclein mutated to adenine at position 209, does not reasonably provide enablement for any mutated human alpha-synuclein or homolog thereof or any other mutation at position 209. Claim 57 has been amended to recite that an adenine replaces a guanine at position 209, and is believed to be free of the rejection. Claim 1 has been amended to delete the term "homologue."

The rejection of claims 1-4 is traversed for the following reasons.

First, it is respectfully submitted that there are only a limited number of possible mutations at position 209, and thus a limited number of mutations to be made and used. There are only two possible mutations other than adenine for guanine, that is thymine for guanine and

cytosine for guanine. It is easily within the skill of an ordinary artisan to make and test for these possibilities without undue experimentation.

Accordingly, it is submitted that claim 4 is clearly enabled. Reconsideration and withdrawal of the rejection with respect to claims 4 is accordingly requested.

Second, it is respectfully submitted that persons of skill in the art will be able, using the methods described in the specification and the general knowledge of the art, to make and use the nucleic acids of claims 1-3, without undue experimentation.

Applicants have provided two articles in the March 12, 2004 response demonstrating that OTHER missense mutations in the alpha-synuclein gene can cause Parkinson's disease.

They are:

Kruger et al. Ala30Pro mutation in the gene encoding alpha-synuclein in Parkinson's disease. Nature Genetics, 18:106-108, 1998.

Zarranz et al. The New Mutation, E36K, of alpha-synuclein causes Parkinson and Lewy Body Dementia. Ann Neurol 55:164-173, 2004.

It is respectfully submitted that these references present convincing evidence that other such mutations can be made and used without undue experimentation. The Examiner has taken the position that a skilled artisan would not have known how to use the Ala30Pro mutation or the Glu36Lys mutation for diagnosing Parkinson's Disease. Applicants respectfully submit that these mutations would be discoverable by routine experimentation using the methods of the present invention, and that they are clearly included within the scope of what was in possession of the present inventors at the time the application was filed. Reconsideration and withdrawal of the rejection of claims 1-4 are respectfully requested.

Claims 1-4 and 57 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claim 57 has been amended to recite that an adenine replaces a guanine at position 209, and is believed to be free of the rejection. Claim 1 has been amended to delete the term "homologue."

The rejection of claims 1-4 is traversed for the following reasons.

First, with respect to claim 4, it is respectfully submitted that the description provided in the specification is clearly adequate to cover the limited number of variants containing a mutation at position 209. As outlined above, such variants can be easily made and tested given the level of knowledge in the art and the teachings of the present specification. Accordingly, reconsideration and withdrawal of the rejection of claim 4 are respectfully requested.

Furthermore, as noted above, two articles subsequent to the present disclosure demonstrate that OTHER missense mutations in the alpha-synuclein gene can cause Parkinson's disease. It is respectfully submitted that this provides ample evidence that persons of skill in the art would be able to practice the invention as claimed in claims 1-3.


Accordingly, it is respectfully submitted that the presently claimed invention meets both the written description and the enablement requirements for patentability. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim 61 was objected to as being dependent upon a rejected base claim (Claim 57). It is believed that claim 57, as presently amended, is in allowable form, and that therefore claim 61 is allowable. Reconsideration and withdrawal of the rejection is respectfully requested.

All rejections having been addressed, it is respectfully submitted that the application is in order for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

Date: February 18, 2004



Ann S. Hobbs (Reg. No. 36,830)
Venable
P.O. Box 34385
Washington, D.C. 20043-9998

Telephone: (202)-344-4651
Telefax: (202)-344-8300